

Applicants: Robert W. Adler et al.

Serial No.: 09/814,251

Page 8

**REMARKS**

Claim 6 was rejected under 35 USC 112, second paragraph as being redundant. Claim 6 has been cancelled.

The Examiner indicates that Figures 8a-8C were not included with the filing of the present application. Applicant has included a full set of drawings, including those indicated as missing and respectfully requests that they be added to the file. No new matter has been added. Applicant also notes that Provisional application 60/191,075, was filed on March 21, 2000 and the present application claims the benefit of that provisional filing. By the present amendment, the provisional application has been formally incorporated by reference and forms an alternative basis to introduce the Figures, which were submitted with the provisional filing.

Claims 1, 3, 4 and 6-9 were rejected under 35 USC 102(b) as being anticipated by Gunderson. Claims 5, 10 and 11 were rejected under 35 USC 103(a) as being unpatentable over Gunderson in view of Rossing. These rejections are respectfully traversed.

By the above amendments, claim 3 has been cancelled and its elements added to independent claim 1. Claims 4 and 5 have been rewritten in independent form and include all of the elements of former claim 1. Applicant respectfully asserts that the amended claims are allowable over the references of record.

Gunderson teaches a method and apparatus for discriminating between tachycardia and fibrillation that measures the intervals separating depolarizations, sorts the intervals into ranges and based on the distribution of ranges, identifies tachycardia or fibrillation. The reference fails to teach "means for defining a discrimination criterion based on determining whether designated ones of the plurality of interval range bins have at least a predetermined threshold number of measured depolarization intervals within them." Specifically, the reference fails to teach an apparatus wherein "the threshold number is set as

Applicants: Robert W. Cadler et al.

Serial No.: 09/814,251

Page 9

a value which increases as an inverse function of the length of the intervals between depolarizations," as specified in claim 1.

Likewise, the reference fails to teach an apparatus "wherein the threshold number is set as a value which increases as an inverse function of a defined percentile of the length of intervals over a sequence of a predetermined number of intervals between depolarizations," as specified in claim 4. Nor does the reference teach an apparatus wherein the "threshold number is set as a value which increases as an inverse function of the 75th percentile of the length of intervals over a sequence of a predetermined number of intervals between depolarizations," as specified in claim 5. These particular threshold determinations serve to further increase the accuracy of the arrhythmia determination. As such, Gunderson fails to anticipate these claims.

With respect to amended claims 1 and 4, the Examiner asserts that these elements are shown in Gunderson at Col. 2, line 63 to Col. 3, line 25. A careful reading of these sections clearly indicates that such teachings are absent. That is, Gunderson does teach sorting events into bins and making a determination as to the particular arrhythmia; however, there is no teaching as to setting the threshold number based on inverse functioning criteria presently claimed.

With respect to claim 5, the Office Action indicates that Gunderson fails to teach "the threshold value increasing as a function of the 75<sup>th</sup> percentile of the length of the intervals of a predetermined number of intervals." The Examiner then asserts that Rossing provides such a teaching.

As previously discussed, Rossing discloses a technique wherein a programmable fibrillation detection interval range and a programmable tachycardia detection interval range are adjacent to one another. In particular, the interval range designated as indicative of fibrillation consists of intervals less than a programmable interval (FDI) and the interval range designated as indicative of ventricular tachycardia consists of intervals less than a programmable interval (TDI) and greater than or equal to FDI. Measured R-R intervals, out of a preceding series of a predetermined number (FEB) of intervals,

Applicants: Robert W. Stadler et al.  
Serial No.: 09/814,251  
Page 10

falling within each of these two ranges are separately counted. That is, a count (VTEC) of R-R intervals falling within the tachycardia interval range, and a count (VFEC) of the number of intervals falling within the fibrillation interval range are made. VTEC is incremented in response to R-R intervals that are greater than or equal to FDI but shorter than TDI, and is reset to zero in response to intervals greater than or equal to TDI and is insensitive to intervals less than FDI. VTEC is compared to a programmed value (VTNID) and VFEC is compared to a corresponding programmable value (VFNID). When one of the counts equals its corresponding programmable value, the criterion for the presence of the corresponding arrhythmia, i.e. fibrillation or tachycardia, is met. An appropriate therapy, e.g., anti-tachycardia pacing, a cardioversion pulse or a defibrillation pulse, is then delivered. Whereas Rossing discriminates on the basis of determining which of two interval ranges has the most counts, the present invention examines the relative distribution of the measured depolarization intervals.

The Examiner appears to have focused on the binary criteria disclosed by Rossing that indicates when one of the other of the intervals has been satisfied. That is, if, for example, 50% or 75% of the recorded events fall within a given interval, then the appropriate counter is incremented (Col. 4, lines 4-17). This does not teach an apparatus wherein the "threshold number is set as a value which increases as an inverse function of the 75th percentile of the length of intervals over a sequence of a predetermined number of intervals between depolarizations," as specified in claim 5. As such, this reference fails to remedy the deficiencies noted in Gunderson.

#### **RESPONSE TO ADVISORY ACTION**

In the Advisory Action, the Examiner disagrees with the Applicant's characterization of the Gunderson and Rossing references and essentially maintains the previous basis for rejection. Applicant respectfully asserts that

Applicants: Robert W. Stadler et al.

Serial No.: 09/814,251

Page 11

after reviewing the amended claims and the portions of the references relied on, the Examiner appears to be confusing two different concepts from the claims.

Specifically, claim 1 includes "means for defining a discrimination criterion based on determining whether designated ones of the plurality of interval range bins have at least a predetermined threshold number of measured depolarization intervals within them, wherein the threshold number is set as a value which increases as an inverse function of the length of the intervals between depolarizations." The "threshold number" therefore is the number of cardiac events in a given bin that satisfy a criteria. That "threshold number" will vary from bin to bin based on the claimed relationship. For example, in claim 1 the threshold number is set as a value that increases as an inverse function of the length of the intervals between depolarizations.

The Examiner appears to rely on the fact that the various bins in both the presently claimed invention and the Gunderson reference represent cardiac events having progressively shorter intervals, thus representing the nature of the cardiac event. For example, faster events, i.e., shorter intervals may be more indicative of fibrillation while somewhat slower events, i.e., somewhat longer intervals may be more indicative of tachycardia. That is all that is discussed at Col. 2, line 63- Col. 3, line 9 of the reference. The threshold value in the reference is set to some fixed predetermined value (e.g., 14) and is not varied from bin to bin as presently claimed. The reference does not address adjusting the threshold value in any way. The mere suggestion that such parameters can be set during manufacture or by a physician does not teach the claimed criteria for setting the threshold number.

There is no teaching or suggestion in the cited references to vary the threshold value according to the presently claimed parameters. Thus, Gunderson does not anticipate the claims and the combination of Gunderson and Rossing do not render the claims obvious.


Applicants: Robert W. Stadler et al.

Serial No.: 09/814,251

Page 12

In consideration of the amendments to the claims and the remarks presented herein, Applicant submits that all pending claims are now in condition for allowance and requests that a notice of allowance issue in due course.

Respectfully submitted,

6/16/03  
Date  
Atty: Daniel G. Chapik

Reg. No. 43,424

(763) 514-3066



27581

SEP. 16..2003 1:45PM

MEDTRONIC LAW DEPT

NO. 7358 P. 15/15

The "RECEIVED" stamp of the United States Patent and Trademark Office Imprinted  
hereon acknowledges receipt of:

X Amendment Transmittal  
X Amendment

In re Application of: Robert W. Stadler et al.  
For: METHOD AND APPARATUS FOR DETECTION AND TREATMENT OF  
TACHYCARDIA AND FIBRILLATION  
Serial No.: 09/814,251  
Filed: March 21, 2001

DOCKET: P-8777.00  
DGC/mc

MAILED: June 16, 2003